



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,808	08/25/2003	Jongyoon Han	SD-8401.1	1313
51917 7590 06/15/2007 SMITH, GAMBRELL & RUSSELL (SNL) 1850 M STREET, NW # 800 WASHINGTON, DC 20036			EXAMINER NOGUEROLA, ALEXANDER STEPHAN	
			ART UNIT 1753	PAPER NUMBER
			NOTIFICATION DATE 06/15/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ssundby@sgrlaw.com  
dcdocketing@sgrlaw.com

# Office Action Summary

Application No.

10/646,808

Applicant(s)

HAN ET AL.

Examiner

ALEX NOGUEROLA

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 41-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/20/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Response to Amendment***

1. Applicant's amendment of March 20, 2007 does not render the application allowable.

***Status of the Rejections pending since the Office action of  
November 07, 2006***

2. All previous rejections are withdrawn.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1753

6. Claims 41-43, 45-48, 53-59, 65, 67, 70, 77-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al. WO 02/48177 A1 ("Sanders") in view of Lee et al. (US 6,652,918 B1) ("Lee") and Burns et al. (US 7,005,050 B2) ("Burns") (note that priority is claimed from provisional application 60/3246, 214, filed on October 24, 2001).

Addressing claim 41, Sanders discloses a multidimensional electrophoresis device (Figure 1) comprising a IEF (isoelectric focusing) gel having a predefined pH gradient (page 03:23 – page 04:02) in fluidic communication with a microchannel having at least one solid gel having a pore size (implied by page 04:04-08, which discloses providing an electrophoresis gel in the separation channel).

Sanders does not mention whether the gel having the predefined pH gradient includes ampholyte material. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to include ampholytes in the IEF gel because as taught by Lee gel strips having a pH gradient "... are typically obtained by electrophorescing [sic] carrier ampholytes through the gel or by covalently incorporating a gradient of acidic and basic buffering groups when the gel strip is cast. [emphasis added]" See col. 01:49-56.

Sanders also does not mention whether the solid gel having a pore size was made by photopolymerization. As a first matter, how the solid gel was made is a product-by-process limitation that does not structurally or compositionally differentiate the claimed solid gel from that Sanders without some showing by Applicants. Burns discloses a method for photopolymerizing gel in situ in a microchannel. See the

Art Unit: 1753

abstract and Figures 1A-1D. It would have been obvious to one with ordinary skill in the art at the time of the invention to photopolymerize the solid gel as taught by Burns in the invention of Sanders because as taught by Burns

... it is believed the use of photopolymerized polymer (e.g., polyacrylamide) sieving matrices overcomes many of the drawbacks of conventional polyacrylamide gel preparation. The present invention can reproducibly resolve a dsDNA standard of about 20 bp well into about the 500bp range in just a few millimeters. The individual bands are clearly observed and appear essentially identical to a macro-scale electrophoresis separation. Since varying the polymer polymerization time strongly influences the structure and sieving properties of the polymerized polymer, a further potential advantage of the UV initiated chemistry of the present invention is the ability to tailor the pore structure of a single polymer by appropriate modulation of polymerization conditions. See col. 03:04-18.

Other benefits are disclosed in col. 03:40-49 of Burns.

Addressing claims 42 and 43, for the additional limitations of these claims see Figure 1 in Sanders and note that element 14 is the ampholyte material and element 16 is the solid gel.

Addressing claims 45, for the additional limitation of this claim see in Sanders page 06:09-19 and page 04:03-08 (note "... *normally* with no pH gradient.", which implies that it could have a pH gradient and thus be suitable for use in IEF) and in Burns col. 02:60-67; col. 01:66 – col. 02:05; and col. 10:42-46, which discloses polyacrylamide gel for gel electrophoresis that could be used for PAGE or SDS-PAGE.

Addressing claims 46, for the additional limitation of this claim see in Sanders page 03:22 – page 04:02 and page 06:09-19.

Addressing claims 47 and 48, for the additional limitations of these claims first note that how the solid gel was made is a product-by-process limitation that does not structurally or compositionally differentiate the claimed solid gel from that Sanders without some showing by Applicants. In any event, Sanders as modified by Lee and Burns meets the additional limitations of these claims. See in Sanders page 04:04-08 and in Burns col. 02:60-67 and col. 05:34-45.

Addressing claims 53-57, Sanders does not mention having the length be within the claimed ranges; however, Sanders does disclose having the device be only 40 mm x 40 mm and that the microchannel may be straight or curved. See Figure 1; page 10, lines 16-19; and page 03, lines 23-24. Thus, barring evidence to the contrary, such as unexpected results, the claimed length ranges are either arbitrary, or just a matter of optimizing the microchannel length for improved separation to provide a smaller pH gradient, that is many isoelectric sections, or to increase the separation path for the gel electrophoresis, which will improve the resolution of the sample components.

Addressing claims 58 and 59, for the additional limitations of these claims see in Sanders page 05:25-26.

Addressing claims 65 and 67, for the additional limitations of these claims see in Sanders page 03:22 – page 04:09 and page 06:07-19.

Addressing claim 70, the additional limitation of this claim just appears to require using the device of Sanders as modified by Lee and Burns as intended.

Addressing claims 72-76, Sanders does not mention the time for performing IEF, SDS-PAGE, or native PAGE, although Sanders does disclose measuring analyte velocity. See page 09, second full paragraph. However, barring evidence to the contrary, such as unexpected results, the time for performing one of these separations will depend on the desired resolution and separation conditions optimized for this resolution. For example, it was known in the art that the higher the electrophoresis voltage the quicker the separation, however, resolution would be adversely affected at higher voltages because of Joule heating. Also, a shorter microchannel lengths will



Art Unit: 1753

reduce the separation time however the separation resolution will not be as great as for longer microchannels, other things being equal.

Addressing claim 77, for the additional limitation of this claim see in Sanders page 01:04-06.

Addressing claim 78, for the additional limitation of this claim see in Sanders page 01:01-24 and page 06:07-19.

Addressing claim 79, for the additional limitation of this claim see in Sanders page 05, lines 26-27, which discloses introducing sample into the end of the focusing section. This implies a device for introducing sample, such as at least a syringe or pipette.

Addressing claim 80, for the additional limitation of this claim see in Sanders page 06:08-15 and page 06:25 – page 07:06.

7. Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al. WO 02/48177 A1 ("Sanders") in view of Lee et al. (US 6,652,918

Art Unit: 1753

B1) ("Lee") and Burns et al. (US 7,005,050 B2) ("Burns") (note that priority is claimed from provisional application 60/3246, 214, filed on October 24, 2001) as applied to claims 41-43, 45-48, 53-59, 72-80 above, and further in view of Heller (US 6,488,832 B2) ("Heller").

Sanders as modified by Lee and Burns does not disclose a gradient gel as claimed, although it should be noted that Burns discloses a range of gel concentrations of between 4 and 15% (w/v). See col. 04:39-47.

Heller discloses, "Gradient gel electrophoresis is a technique in which a gel matrix having an increasing concentration of polyacrylamide (3% to 40%) along the separation axis is used to separate macromolecules in a wide range of sizes." See col. 02:53 – col. 03:55.

It would have been obvious to one with ordinary skill in the art at the time of the invention to have the solid sieving materials be of varying concentration as taught by Heller in the invention of Sanders as modified by Lee and Burns because this will optimize the separation conditions for the samples. For example, Heller discloses that DNA separation can be optimized with a solid sieving material of varying concentration. See col. 03:06-56. As for the concentration being between about 4% to about 20%, this is within the range disclosed by Heller and so barring a showing of unexpected results just further optimization of the sieving material for the expected sample types.

8. Claims 41-50, 53-57, 60-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 6,974,526 B) ("Lee II") in view of Burns et al. (US 7,005,050 B2) ("Burns") (note that priority is claimed from provisional application 60/3246, 214, filed on October 24, 2001).

Addressing claim 41, Lee II discloses a multidimensional electrophoresis device (Figures 1-10) comprising ampholyte material (in channel 3, see e.g., col. 05:45-49; col. 06:44-52; and col. 08:44-56) in fluidic communication with a microchannel (4) having at least one solid gel having a pore size (implied by col. 05:45-49 and col. 08:44-56, which discloses providing an electrophoresis gel in the separation channel).

Sanders does not mention making the solid gel having a pore size by photopolymerization. As a first matter, how the solid gel was made is a product-by-process limitation that does not structurally or compositionally differentiate the claimed solid gel from that Sanders without some showing by Applicants. Burns discloses a method for photopolymerizing gel in situ in a microchannel. See the abstract and Figures 1A-1D. It would have been obvious to one with ordinary skill in the art at the time of the invention to photopolymerize the solid gel as taught by Burns in the invention of Lee II because as taught by Burns

... it is believed the use of photopolymerized polymer (e.g., polyacrylamide) sieving matrices overcomes many of the drawbacks of conventional polyacrylamide gel preparation. The present invention can reproducibly resolve a dsDNA standard of about 20 bp well into about the 500bp range in just a few millimeters. The individual bands are clearly observed and appear essentially identical to a macro-scale electrophoresis separation. Since varying the polymer polymerization time strongly influences the structure and sieving properties of the polymerized polymer, a further potential advantage of the UV initiated chemistry

Art Unit: 1753

of the present invention is the ability to tailor the pore structure of a single polymer by appropriate modulation of polymerization conditions. See col. 03:04-18.

Other benefits are disclosed in col. 03:40-49 of Burns.

Addressing claims 42 and 43, for the additional limitations of these claims see Figures 1-10 in Lee II and note that element 3 contains the ampholyte material and element(s) 4 contain the solid gel.

Addressing claim 44, Lee II as modified by Burns does not disclose whether the ampholyte material is a *liquid* polymer gel (although that it is a polymer gel is disclosed). Lee II, though, discloses ampholyte material that is a liquid polymer gel (that is, flowable – page 8 of the Amendment of March 22, 2007). See the abstract and col. 06:53 – col. 07:18. It would have been obvious to use a liquid polymer gel for the ampholyte material as taught by Lee II in the invention of Lee II as modified by Burns because then the ampholyte polymer used could be optimized as the polymer for the ampholyte material could be polyethylene oxide, branched dextran, or another polymer used as ampholyte material, and not just photopolymerizable polymer or a polymer as easily photopolymerized as polyacrylamide. See in Lee II col. 06:60-64. It would not be inconsistent to photopolymerize the solid gel in situ and also flow the gel for the ampholyte material in the intended microchannel because what is more important than how the gels are made is that an optimum gel be used for each separation. As taught

Art Unit: 1753

by Burns one advantage to the photopolymerizable gel is that it can be precisely positioned with a well-defined flat interface. See col. 16:34-43. So a liquid gel could be made adjacent to it. There is a balance between the enhanced resolution and stability of a particular gel and the ease of manufacturing it.

Addressing claims 45-47, for the additional limitations of these claims first note that how the solid gel was made is a product-by-process limitation that does not structurally or compositionally differentiate the claimed solid gel from that Lee II without some showing by Applicants. In any event, Lee II and Burns meets the additional limitations of these claims. See in Lee II col. 01:25-36; col. 02:01-20; col. 08:44 – col. 09:05; and in Burns col. 02:60-67 and col. 05:34-45.

Addressing claim 48, for the additional limitations of this claim see in Lee II col. 01:25-52 and in Burns col. 02:60-67.

Addressing claim 49, for the additional limitations of this claim first note the plurality of second dimension separation channels (4) in Figures 1-10. Lee II as modified by Burns does not appear to appear to disclose having the solid sieving material different in each second dimension microchannel. However, barring a contrary showing, such as unexpected results, to do so is just a matter of optimizing the second dimension separations. If the first dimension separation is for isoelectric focusing than different sample components would be expected in each second dimension microchannel and so the second dimension gels can be optimized accordingly.

Addressing claim 50, for the additional limitations of this claim see in Burns col. 04:39-47.

Addressing claims 53-57, Lee II does not mention having the length be within the claimed ranges; however, Lee II does state, "The microchannels (e.g. 3, 4) can be any suitable length. A preferred length ranges from about 1 to about 10 cm. Other lengths may be used." See col. 05:26-30. Thus, barring evidence to the contrary, such as unexpected results, the claimed length ranges are either arbitrary, or just a matter of optimizing the microchannel length for improved separation to provide a smaller pH gradient, that is many isoelectric sections, or to increase the separation path for the gel electrophoresis, which will improve the resolution of the sample components.

Art Unit: 1753

Addressing claims 58 and 59, for the additional limitations of these claims see in Lee II col. 04:48-51 and Figures 1-10.

Addressing claims 60 and 61, for the additional limitations of these claims note channels 11 and 36 in Figures 6-8 in Lee II.

Addressing claim 62, for the additional limitation of this claim see in Lee II col. 06:05-20.

Addressing claim 63, for the additional limitation of this claim note the embodiments in Figures 8 and 10 of Lee II in which channels "4" and "11" are grouped in threes or fours. One of each group of three or four channels can be construed as a bypass channel for the other channels in the group.

Addressing claim 64, for the additional limitation of this claim see note chamber 5 in Lee II.

Addressing claim 65 and 67, for the additional limitations of these claims see in Lee II col. 06:44-52 and in Burns col. 01:66 – col. 02:05.

Addressing claim 66, for the additional limitation of this claim see in Lee II col. 08:37-43.

Addressing claim 68, for the additional limitation of this claim note "B" in Figure 10.

Addressing claim 69, for the additional limitation of this claim note that the membrane is a polymeric strip that lies across the underlying channels. See Figure 10 in Lee II. If pressure were applied to the membrane it would any channels under the region in which pressure was applied.

Addressing claim 70, the additional limitation of this claim just appears to require using the device of Lee II as modified by Burns as intended.

Addressing claim 71, for the additional limitations of this claim note the embodiment of Figure 7 with multiple electrode reservoirs 10 above IEF channel 3 and corresponding electrode reservoirs 8 below IEF channel 3. Using multiple electrode reservoirs 10 and 8 allows the SDS-PAGE or PAGE microchannels 4 to be grouped so



Art Unit: 1753

that different voltage protocols may be applied to different microchannels. As for the limitation preventing fluid sample from migrating through the vertical microchannel note voltage control channels 36. Since the device of Lee II as modified by Burns is a 2-D dimensional electrophoresis device in which the first dimension separation, IEF focusing is to occur in the horizontal microchannel 3 before the second dimension separation in the vertical channel (col. 05:64 – col. 06:04 and col. 08:44-52) it is clearly obvious to control the voltages across the microchannels so that no sample migrates in a vertical microchannel until the first dimension separation is finished otherwise sample components of the same size, but different pKa will not be separated.

Addressing claims 72-76, Lee does not mention the time for performing IEF, SDS-PAGE, or native PAGE. See col. 02:61-66. However, barring evidence to the contrary, such as unexpected results, the time for performing one of these separations will depend on the desired resolution and separation conditions optimized for this resolution. For example, it was known in the art that the higher the electrophoresis voltage the quicker the separation, however, resolution would be adversely affected at higher voltages because of Joule heating. Also, a shorter microchannel lengths will reduce the separation time however the separation resolution will not be as great as for longer microchannels, other things being equal.

Art Unit: 1753

Addressing claim 77, for the additional limitation of this claim see in Lee II the abstract.

Addressing claim 78, for the additional limitation of this claim see in Lee II col. 01:25-37; col. 06:44-52; and col. 08:44 – col. 09:05.

Addressing claim 79, for the additional limitation of this claim see in Lee II col. 04:48-50, which identified reservoir 5 as an inlet reservoir for the IEF microchannel 3. One with ordinary skill in the art would use at least a common laboratory sampling device such as at least a syringe or pipette to introduce sample into this reservoir.

Addressing claim 80, for the additional limitation of this claim see in Lee II col. 08:44 – col. 09:05.

9. Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 6,974,526 B) ("Lee II") in view of Burns et al. (US 7,005,050 B2) ("Burns") as applied to claims 41-50, 53-80 above, and further in view of Heller (US 6,488,832 B2) ("Heller").

Lee II as modified by Burns does not disclose a gradient gel as claimed, although

Art Unit: 1753

it should be noted that Burns discloses a range of gel concentrations of between 4 and 15% (w/v). See col. 04:39-47.

Heller discloses, "Gradient gel electrophoresis is a technique in which a gel matrix having an increasing concentration of polyacrylamide (3% to 40%) along the separation axis is used to separate macromolecules in a wide range of sizes." See col. 02:53 – col. 03:55.

It would have been obvious to one with ordinary skill in the art at the time of the invention to have the solid sieving materials be of varying concentration as taught by Heller in the invention of Lee II as modified by Burns because this will optimize the separation conditions for the samples. For example, Heller discloses that DNA separation can be optimized with a solid sieving material of varying concentration. See col. 03:06-56. As for the concentration being between about 4% to about 20%, this is within the range disclosed by Heller and so barring a showing of unexpected results just further optimization of the sieving material for the expected sample types.

10. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al. WO 02/48177 A1 ("Sanders") in view of Lee et al. (US 6,652,918 B1) ("Lee") and Burns et al. (US 7,005,050 B2) ("Burns") (note that priority is claimed from provisional

application 60/3246, 214, filed on October 24, 2001) as applied to claims 41-43, 45-48 above, and further in view of Lee et al. (US 6,974,526 B2) ("Lee II").

Sanders as modified by Lee does not disclose whether the ampholyte material is a *liquid* polymer gel (although that it is a polymer gel is disclosed). Lee II discloses a microfluidic system for performing 2-D bimolecular separation in which the ampholyte material is a liquid polymer gel (that is, flowable – page 8 of the Amendment of March 22, 2007). See the abstract and col. 06:53 – col. 07:18. It would have been obvious to use a liquid polymer gel for the ampholyte material as taught by Lee II in the invention of Sanders as modified by Lee and Burns because then the ampholyte polymer used could be optimized as the polymer for the ampholyte material could be polyethylene oxide, branched dextran, or another polymer used as ampholyte material, and not just photopolymerizable polymer or a polymer as easily photopolymerized as polyacrylamide. See in Lee II col. 06:60-64. It would not be inconsistent to photopolymerize the solid gel in situ and also flow the gel for the ampholyte material in the intended microchannel because what is more important than how the gels are made is that an optimum gel be used for each separation. As taught by Burns one advantage to the photopolymerizable gel is that it can be precisely positioned with a well-defined flat interface. See col. 16:34-43. So a liquid gel could be made adjacent to it. There is a balance between the enhanced resolution and stability of a particular gel and the ease of manufacturing it.

***Claim Rejections - 35 USC § 112***

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. No support has been found in the original disclosure for having the ampholyte material be a liquid polymer gel.

13. Claim 45 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. No support has been found in the original disclosure for having ampholyte material in fluidic communication with a microchannel having a solid gel suitable for isoelectric focusing.

14. Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: claim 66 requires the at least one polymeric membrane to isolate at least two microchannels in the same plane, but claim 68 require the polymeric membrane to be formed or placed on top of the microchannels, that is, in a different plane than the plane the microchannels are in. Thus, claim 68 appears to be inconsistent with claim 66.

***Final Rejection***

15. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1753

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1753

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguera  
Primary Examiner  
AU 1753  
June 9, 2007